NISTIR 5122

# More Questions and Answers on the ISO 9000 Standard Series and Related Issues

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NIST

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February 1993

## FOREWORD

The National Institute of Standards and Technology's (NIST)
Standards Code and Information Program periodically publishes
information on various aspects of conformity assessment systems
for use by those who operate or benefit from such systems.  There
has been considerable interest in the content and application of
international standards related to quality management,
particularly ISO 9000 Standard Series.  This report, a sequel to
NISTIR 4721, "Questions and Answers on Quality, the ISO 9000
Standard Series, Quality System Registration, and Related
Issues," provides updated information and answers additional
questions on this topic.  This material is intended for persons
concerned about the ISO 9000 standards and should help foster a
wider interest in the use of quality systems in general.
Appendix A of this document also references other publications
and services provided by the Standards Code and Information
Program which readers may find useful.

The reader is invited to share any comments on the material
presented in this document.

## ACKNOWLEDGEMENTS

# ABSTRACT

This report, a sequel to NISTIR 4721, provides additional information on the ISO 9000 standards and related issues to readers unfamiliar with some of the new developments in this area. It attempts to answer additional questions on ISO 9000 standards related issues which NIST has received since the publication of NISTIR 4721. It also identifies sources for further help in this area.

**Key Words:** conformity assessment; EN 29000; EOTC; ISO Forum; ISO 9000; quality assurance; quality control; quality system; quality system registration

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## INTRODUCTION

Quality improvement has now become a key U.S. domestic and international business strategy, and worldwide interest in quality systems as one method of assuring the consistent conformity of products or services to a defined set of standards or expectations has mushroomed. Nowhere is this more apparent than in the ever increasing international adoption and use of the ISO 9000 Standard Series. Growing demand by both buyers and regulators within and outside the European Community for conformity to ISO 9000 requirements has made these standards and their usage a matter of considerable importance and concern to U.S. companies.

This report, a sequel to NISTIR 4721 - Questions and Answers on Quality, the ISO 9000 Standard Series, Quality System Registration, and Related Issues, attempts to answer additional questions on ISO 9000 standards related issues which the National Institute of Standards and Technology (NIST) has received since the publication of NISTIR 4721. It also identifies sources for further help in this area.

This report is intended for persons involved with or concerned about the ISO 9000 standards and quality system registration. Special attention is given to ISO 9000 related events within the European Community (EC) that might affect U.S. trade.


## WHY AND BY WHOM WERE THE ISO 9000 STANDARDS DEVELOPED?

The International Organization for Standardization (ISO) is a worldwide federation founded in 1946 to promote the development of international standards and related activities (including conformity assessment) to facilitate the exchange of goods and services worldwide. ISO is composed of member bodies from over 90 countries, the U.S. member body being the American National Standards Institute (ANSI).

In 1979, ISO formed Technical Committee (TC) 176 on Quality Management and Quality Assurance to address the worldwide trend towards increasingly stringent customer demands with regard to quality combined with growing confusion in international trade resulting from differing national and subnational quality system requirements.

In 1987, based on the work of TC 176, ISO published the ISO 9000 Standard Series on quality management and assurance. These standards were based on considerable input from a number of countries, especially the United States (U.S.), Canada, and the United Kingdom (U.K.). In particular, the ISO 9000 standards were based in large part on the British Standards Institution's BS 5750 Series, Quality Systems.

## HOW WAS BS 5750 DEVELOPED?

In 1959, the U.S. Department of Defense (DOD) established a Quality Management Program with the designation of MIL-Q-9858. Four years later, it was revised to MIL-Q-9858A - its only revision to date. In 1968, the North Atlantic Treaty Organization (NATO) essentially adopted the provisions of MIL-Q-9858A, Quality Program Requirements, in the form of Allied Quality Assurance Publication 1 (AQAP-1). In 1970, the U.K.'s Ministry of Defence adopted the provisions of AQAP-1 as its Management Program Defence Standard DEF/STAN 05-8.[1] In 1979, the British Standards Institution (BSI) developed the first commercial quality management system standard, known as BS 5750. From these predecessors, ISO created the ISO 9000 Standard Series in 1987 - essentially adopting most of the elements of BS 5750.[2] That same year, the ISO 9000 standards were adopted in the United States as the ANSI/ASQC (American Society for Quality Control) Q90 Standard Series; and BS 5750 was revised to be identical to the ISO 9000 standards. NATO is currently revising its quality system standards to incorporate the ISO 9000 standards.[3]

## WHAT IS THE U.S. ROLE IN ISO TC 176?

The United States has been an active participant in ISO TC 176 since 1987. The ASQC, through ANSI which serves as the U.S. member body in ISO, has been responsible for managing U.S. representation in TC 176. ASQC also has assumed responsibility for managing the adoption of the ISO 9000 and 10000 standards as American National Standards.

According to ISO procedures, all ISO standards, including those in the ISO 9000 Standard Series, must be reviewed and revised or reaffirmed at least once every five years. The initial ISO 9000 standards (ISO 9000, 9001, 9002, 9003, and 9004 without subparts) published in 1987 were scheduled for review in 1992/1993, as was ISO Standard 8402 - Quality - Vocabulary, which contains relevant terminology and definitions. Minor modifications in the original

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[1]/ DEF STAN 05-08 has recently been revised to reflect the provisions of ISO 9001-9004 and has been renumbered DEF/STAN 05-21, 22, 23, and 24.

[2]/ Stephen D. Sawin and Spencer Hutchens, Jr., "ISO-9000 In Operation," 1991 ASQC Quality Congress Transactions, Milwaukee, WI, pp. 915-916.

[3]/ Aerospace Industries Association, Impact of International Standardization and Certification on the U.S. Aerospace Industry, AIA, Washington, DC, April 1992, pg. 7.

ISO 9000 Series are expected in 1993/1994, with major revisions in 1997/1998.[4]

The United States, which adopted the original five ISO 9000 standards in 1987 as the ANSI/ASQC Q90 Series, is actively involved in their review. ASQC is coordinating the development of U.S. comments and positions on the 1992/1993 revisions.

## DOES THE ANSI/ASQC Q90 STANDARD SERIES DIFFER FROM THE ISO 9000 STANDARD SERIES?

ISO 9000-9004 and ANSI/ASQC Q90-94 are technically equivalent. However, the ANSI/ASQC Q90 Series has been modified to incorporate customary American language usage and spelling. Some supplementary guidance on sampling and other statistical methods and product liability and user safety has also been included in the appendices to ANSI/ASQC Q94. ASQC is planning to renumber the ANSI/ASQC Q90 Series as the ANSI/ASQC Q9000 series to clearly indicate their equivalency to the ISO 9000 Series.

## HAVE ANY ISO 9000 OR RELATED STANDARDS BEEN PUBLISHED SINCE 1987?

ISO has continued to supplement the ISO 9000 Series. Some of these standards have been included as parts under ISO 9000 and ISO 9004, while others have been included in the new ISO 10000 Series. Both the ISO 9000 and 10000 Standards Series have been reserved for use by ISO TC 176.

Recently released ISO standards and guidelines in the quality area include:

ISO 9000-3, GUIDELINES FOR THE APPLICATION OF ISO 9001 TO THE DEVELOPMENT, SUPPLY AND MAINTENANCE OF SOFTWARE (1991).

ISO 9004-2, QUALITY MANAGEMENT AND QUALITY SYSTEM ELEMENTS - PART 2: GUIDELINES FOR SERVICES (1991).

ISO 10011 PART 1, GUIDELINES FOR AUDITING QUALITY SYSTEMS - AUDITING (1990).

ISO 10011 PART 2, GUIDELINES FOR AUDITING QUALITY SYSTEMS - QUALIFICATION CRITERIA FOR AUDITORS (1991).

ISO 10011 PART 3, GUIDELINES FOR AUDITING QUALITY SYSTEMS - MANAGING AUDIT PROGRAMS (1991).

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[4]/ These latter revisions are also referred to as the Phase 2 revisions.

ISO 10012-1, QUALITY ASSURANCE REQUIREMENTS FOR MEASURING
EQUIPMENT - PART 1: MANAGEMENT OF MEASURING EQUIPMENT (1992).


## WHAT IS ISO TC 176 WORKING ON?

The following standards are under development in TC 176's
subcommittees (SC):[5]

### SC 1 - TERMINOLOGY

o DRAFT INTERNATIONAL STANDARD (DIS) 8402-1 QUALITY SYSTEMS
   TERMINOLOGY

### SC 2 -QUALITY SYSTEMS

o DRAFT INTERNATIONAL STANDARD (DIS) 9004-3, QUALITY MANAGEMENT
   AND QUALITY SYSTEM ELEMENTS - PART 3: GUIDELINES FOR PROCESSED
   MATERIALS (Will be published mid to late 1993.)
o DRAFT INTERNATIONAL STANDARD (DIS) 9000-2, QUALITY MANAGEMENT
   AND QUALITY SYSTEM STANDARDS - PART 2: GENERIC GUIDELINES FOR
   THE APPLICATION OF ISO 9001, ISO 9002, AND ISO 9003 (Will be
   published mid to late 1993.)
o DRAFT INTERNATIONAL STANDARD (DIS) 9004-4, QUALITY MANAGEMENT
   AND QUALITY SYSTEM ELEMENTS - PART 4: GUIDELINES FOR QUALITY
   IMPROVEMENT (Will be published mid to late 1993.)
o COMMITTEE DRAFTS (CD) 9000-1, 9002, 9003, AND 9004-1, REVISIONS
   TO ISO 9000, 9001, 9002, 9003, AND 9004 (Expected to be out for
   DIS ballot shortly.)
o COMMITTEE DRAFT (CD) 9004-6, QUALITY MANAGEMENT AND QUALITY
   SYSTEM ELEMENTS - PART 6: GUIDELINES QUALITY PLANS
o WORKING DRAFT (WD) 9004-5, QUALITY MANAGEMENT AND QUALITY
   SYSTEM ELEMENTS - PART 5: GUIDE TO QUALITY ASSURANCE FOR
   PROJECT MANAGEMENT
o COMMITTEE DRAFT (CD) 9004-7, QUALITY MANAGEMENT AND QUALITY
   SYSTEM ELEMENTS - PART 7: GUIDELINES FOR CONFIGURATION
   MANAGEMENT

### SC 3 - QUALITY TECHNOLOGIES

o WORKING DRAFT (WD) 10012-2: QUALITY ASSURANCE REQUIREMENTS FOR
   MEASURING EQUIPMENT - PART 2: MEASURING ASSURANCE

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[5]/ Information on draft or proposed standards work was
provided by Patricia Kopp, Standards Administrator, American
Society for Quality Control (ASQC), Milwaukee, WI.

Development of Draft International Standard (DIS) 9000-4, Quality
Management and Quality System Standards - Part 4: Application for
Dependability Management, is being handled by the International
Electrotechnical Commission (IEC).

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o COMMITTEE DRAFT (CD) 10013: GUIDELINES FOR DEVELOPING QUALITY
  MANUALS (Expected to be out for DIS ballot shortly.)
o WORKING DRAFT (WD) 10014: GUIDE TO THE ECONOMIC EFFECTS OF
  QUALITY
o WORKING DRAFT (WD) 10015: CONTINUING EDUCATION AND TRAINING
  GUIDELINES

## WHERE CAN ADDITIONAL INFORMATION ON THE WORK OF ISO TC 176 BE OBTAINED?

Information on ISO Technical Committee 176 (the committee
responsible for the development of the ISO 9000 and 10000
Standard Series) can be obtained from:

> The American Society for Quality Control (ASQC)
> 611 East Wisconsin Ave.
> Milwaukee, WI 53202
> Phone: 414-272-8575 or 1-800-248-1946 (U.S. and Canada)
> Fax: 414-272-1734

## WHERE CAN COPIES OF THESE NEW STANDARDS BE OBTAINED?

Copies of ISO draft/final standards and European standards (ENs)
can be purchased from:[6]

> The American National Standards Institute
> 11 West 42nd Street, 13th Floor
> New York, NY 10036
> Phone: (212) 642-4900, Fax: (212) 302-1286

Other standards sources are listed in Appendix B.

## WHAT COUNTRIES HAVE ADOPTED THE ISO 9000 STANDARD SERIES?[7]

According to information collected by ISO (as of October 20,
1991) and updated as of September, 1992,[8] the EC and fifty-six

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[6]/ NOTE: Identify draft international standards (DIS) as
such when requesting copies from ANSI. .

[7]/ The International Electrotechnical Commission's (IEC)
Quality Assessment System for Electronic Components (also known
as the IECQ System) also requires that component manufacturers
(who wish to add products to the IECQ's Qualified Product List)
comply with the requirements of ISO 9000.  To contact the IEQC
Program, see Appendix D.

[8]/ Robert W. Peach, The ISO 9000 Handbook, CEEM, Virginia,
1992, p. 4.  These six additional countries are identified by a
single asterisk.

countries have or are expected to soon adopt the ISO 9000
Standard Series as voluntary national standards.   The list
includes:

| | | | |
|---|---|---|---|
| Algeria | European | Malaysia | Spain |
| *Argentina | Community | *Mexico | Sweden |
| Australia | Finland | Netherlands | Switzerland |
| Austria | France | New Zealand | Tanzania |
| *Barbados | Germany | Norway | Thailand |
| Belgium | Greece | Pakistan | Trinidad/Tobago |
| *Brazil | Hungary | Philippines | Tunisia |
| Canada | Iceland | Poland | Turkey |
| Chile | India | Portugal | United Kingdom |
| *China | Ireland | Romania | United States |
| Columbia | Israel | Russia | Venezuela |
| Cuba | Italy | **Saudi Arabia | Yugoslavia |
| Cyprus | Jamaica | Singapore | Zimbabwe |
| Czechoslovakia | Japan | South Africa | |
| Denmark | Luxembourg | *South Korea | |

**ISO 9000 standards are in the process of being adopted by the
Saudi Arabian Standards Organization (SASO).

## WHAT ARE THE NUMBERING SYSTEMS USED BY COUNTRIES TO DESIGNATE THE ISO STANDARD SERIES?

Countries adopting the ISO 9000 standards assign numbers to the
standards based on their own national standards numbering
systems.  As noted in the following examples, these numbers may
be very different from those numbers assigned by ISO to the
Series, even though the standards are identical.

In the United States, the ISO 9000 Standard Series has been
adopted as the ANSI/ASQC Q90 Series (soon to be changed to the
ANSI/ASQC Q9000 Series).  In Europe, it has been adopted by the
European Committee for Standardization (CEN) and the European
Committee for Electrotechnical Standardization (CENELEC) as the
European Norm (EN) 29000 Series.  In the U.K., it is BS 5750
Parts 0 to 3.  In Pakistan, it is the PS 3000-3004 Series.  In
Tanzania, they are TZS 500-504; while in China, they are GB/T
10300.1 - 10300.5.

## WHAT IS NEW WITH THE ISO 9000 FORUM?

ISO 9000 Forum symposia have recently been held in a number of
countries on issues related to quality assurance and quality
management.  In addition, the Forum has begun issuing a
newsletter, the ISO 9000 News.  Subscriptions are available from
ANSI.  The ISO Forum was established to serve the needs of ISO

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9000 users by: providing information; facilitating international discussions on new developments and issues affecting the application of the ISO 9000 standards; promoting the exchange of experience in such areas as training, promotion and operation of relevant schemes; harmonizing practices in the application and interpretation of the ISO 9000 standards; and providing advice to ISO TC 176 or the relevant ISO decision making body.

## WHAT ARE "NEW APPROACH" DIRECTIVES?

The Commission of the European Community (EC) has established a conformity assessment scheme for EC-regulated products.[9]  The EC has specified conformity assessment methods in terms of eight "modules," such as the supplier's declaration of conformity (formerly known as self-certification), type testing, quality system approval, or final product verification by a third party. Each "new approach" directive specifies the alternative means (set of modules) that suppliers may use to certify their products as being in conformance with the "essential requirements" spelled out in each directive.

The distinction between "old approach" and "new approach" directives is that "old approach" directives defined all the required technical characteristics of a product within the directive, while the "new approach" directives specify only the more generalized "essential requirements" necessary to protect consumer health and safety and the environment.  The task of actually writing the specific technical requirements is left to the three European standards-setting organizations - CEN, the European Committee for Standardization; CENELEC, the European Organization for Electrotechnical Standardization, and ETSI, the European Telecommunications Standards Institute.

## WHAT IS QUALITY SYSTEM REGISTRATION/APPROVAL AND HOW DOES IT RELATE TO CONFORMITY ASSESSMENT?

Quality system registration or approval involves the assessment and periodic audit of the adequacy of a supplier's quality system by a third party, known as a quality system registrar.  When a supplier's system conforms to the registrar's interpretation of an ISO 9000 or other appropriate standard, the registrar issues the supplier a "certificate of registration."  Note that the supplier's quality <u>system</u> is registered, not an individual

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[9]/  Regulated products are those for which the EC Commission has developed or is developing an EC-wide technical harmonization directive which provides manufacturers with a single set of requirements for products offered for sale in the EC.

product. **Consequently, quality system registration does not imply product conformity to any given set of requirements.**

Conformity assessment, a more comprehensive term, is the systematic evaluation of a product, process, or service to determine the extent to which it complies with specified requirements. Conformity assessment activities include: quality system registration; product or service testing and/or certification; and laboratory, certification body or quality system registrar accreditation.[10]

## WHAT IS THE DIFFERENCE BETWEEN QUALITY SYSTEM CERTIFICATION AND QUALITY SYSTEM REGISTRATION?

These terms are frequently used interchangeably; however, confusion arises when "quality system" is not placed in front of the term "certification." If these two words are missing, it is easy to confuse the assessment and approval of a manufacturer's quality system with product certification[11] -- two entirely different activities! For that reason, ISO/IEC Guide 48 (see Appendix C), the international document which governs the third-party assessment and registration process for quality systems, refers throughout to "registration," not to "certification. The Directory of Quality System Registration Bodies, published by ISO, confirms the Guide 48 terminology.

## WILL QUALITY SYSTEM APPROVALS BE MANDATORY IN THE EC?

Having an approved quality system will not be a blanket requirement for all products. However, approval of a supplier's quality system will be a key component of the EC's legal requirements for product certification in these areas: construction products (9002 or 9003); active implantable medical devices (9001 or 9002); personal protective equipment (9002 or 9003); telecommunications terminal equipment (9001 or 9002); gas appliances (9002); non-automatic weighing instruments (9002); medical devices (9001 or 9002); elevators (9001 or 9002); pressure equipment (9001 or 9002); recreational craft (9001 or 9002); cable ways equipment (9001); measuring and testing

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[10]/ Accreditation is the procedure by which an authoritative body gives formal recognition that a laboratory, certification body, or quality system registrar is competent to conduct specified conformity assessment tasks.

[11]/ Product certification is the procedure by which a third party gives written assurance that a PRODUCT conforms to specified requirements.

instruments (9001, 9002, or 9003); equipment for use in potentially explosive atmospheres (9001 or 9002); and furniture flammability (9002). For most of these regulated products, quality system approval is one approach to proving compliance, not an absolute requirement. Other methods, not involving quality system approval, may also be allowed under these directives.

For example, under the telecommunications terminal equipment directive, a manufacturer has three options for proving conformity to the essential requirement contained in the directive: (1) EC type examination/approval of the product by a notified body plus manufacturer's declaration of conformity to type (whereby a notified body carries out product checks at random intervals); (2) EC type examination of product by a notified body plus approval by a notified body of a manufacturer's quality system according to ISO 9002 (EN 29002); and (3) approval by a notified body of a manufacturer's quality system according to ISO 9001 (EN 29001) with no type approval required.[12] Method 1 does not require any type of quality system approval, while methods 2 and 3 do.

It should be noted that manufacturer compliance with ISO 9002 or ISO 9003 is usually combined with some type of product testing for full product certification to EC requirements. The full quality assurance (ISO 9001) option includes an assessment of the product's design to assure that it conforms to the applicable "essential requirements."

In other directives, such as the Council Directive dated June 14, 1989 on machinery (89/392/EEC), manufacturers of some products are permitted to self-declare that their product conforms to the requirements of the directive and to place the European Community (CE) mark on the product. However, such machinery manufacturers must maintain a file on the manufacture of those products, including information on "the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive" -- in other words, on the manufacturer's quality system. It is possible that the ISO 9000 (EN 29000) Standard Series could be used within the European Community to evaluate the adequacy of such quality systems. However, at the present time, no requirement is included in the manufacturer self-declaration for third party review/approval of the manufacturer's quality system.

Manufacturers need to review **all** relevant EC directives for specific requirements applicable to their products. Each directive requires the use of different methods for proving conformity. It may be that some conformity assessment options,

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[12]/ Mary Saunders, "EC-Wide Certification of Telecom Terminal Equipment Scheduled to Start in November," Europe Now, ITA/DoC, July/August 1992 issue, pg. 4.

while meeting the requirements of one directive, will not meet the requirements of other relevant directives covering a product. A product must meet the conformity assessment requirements of **all** applicable directives for suppliers to be able to apply the CE mark to that product. For some products, specific conformity assessment methods, such as product type testing combined with having an approved quality system, could end up being the only method that will comply with all requirements contained in all applicable directives.

## HOW DOES THE EC PRODUCT SAFETY DIRECTIVE RELATE TO ISO 9000?

The EC Directive on General Product Safety 92/59 (commonly known as the Product Safety Directive) was approved by the EC Council on June 29, 1992. This directive covers **all** products placed on the EC market -- whether regulated by the EC or not. The directive becomes fully operational in June 1994 and applies to the safety of products from the time that they are first placed on the EC market and extends throughout the product's foreseeable life. This requires that the safety of a marketed product be monitored by member states over the product's entire life. The directive covers both new and reconditioned products, though not secondhand products clearly identified as antiques or in need of repair or reconditioning.

The objective of the directive is to impose a general requirement on producers to introduce only safe products into the EC market. A "safe product" is defined as "a product that does not present, in particular in respect of its design, composition, execution, functioning, wrapping, conditions of assembly, maintenance or disposal, instructions for handling and use, or any other of its properties, an unacceptable risk for the safety and health of persons, either directly or indirectly, in particular through its effect upon other products or its combinations therewith."

The Directive requires that products intended for consumers not present any unacceptable risks and that potential users of such products are adequately warned of any remaining risks. Some guidance on what is a safe product is contained in the directive. For that reason, it is probably advisable to read this directive in conjunction with the EC Product Liability Directive discussed below. In general, the Product Safety Directive will not apply to those safety aspects of a product or category of products already covered under an EC directive.

When read in conjunction with the Product Liability Directive, this directive may have some implications for suppliers regarding their quality systems. In the event of legal claims, some legal opinion has suggested that ISO 9000 registration combined with other appropriate technical documentation related to product

safety and adequate product labeling/user instructions could prove useful in a legal defense.[13]


## HOW DOES THE EC PRODUCT LIABILITY DIRECTIVE RELATE TO ISO 9000?

On July 25, 1985, the EC Council ratified a Directive Concerning Liability for Defective Products 85/374 (generally known as the Product Liability Directive).[14] Under this directive, products are considered to be defective when they do not provide the level of safety that the public has a right to expect. That level of safety is more clearly defined for some products in other EC directives, such as the Medical Device Directive and the Machine Safety Directive.

Under the Product Liability Directive, an injured consumer must show the damage experienced, the product defect responsible for the problem, and the relationship between them, although negligence does not have to be proved if the manufacturer could have reasonably foreseen the problem. It is not necessary to prove that a product is unreasonably defective. The directive creates a strict liability and introduces a uniform concept of product liability in some EC nations where such a view did not previously exist. As a result, this directive will affect almost every company doing business in the EC to some degree.

Again, some legal opinion has indicated that while ISO 9000 registration will not protect a company from being sued for a defective product, quality system documentation creates a technical record that could be useful in such prospective product liability suits.[15]

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[13]/ Gregory G. Scott and Dr. James W. Kolka, European Community Product Liability and Product Safety Directives, CEEM, Virginia, 1992.

[14]/ In November 1990, the EC Commission also proposed a Directive on the Liability of Suppliers of Services (90)482, known as the Services Liability Directive. This directive, which is intended to complement the Product Liability Directive, has not yet been passed.

[15]/ Gregory G. Scott and Dr. James W. Kolka, European Community Product Liability and Product Safety Directives, CEEM, Virginia, 1992.

## HOW DOES THE ISO 9000 STANDARD SERIES APPLY TO THE EC SERVICES SECTOR?

There is no reference to ISO 9000, or to "quality management systems," in EC legislation related to private sector procurement of services, such as accounting, engineering or legal services. The proposed EC directive on procedures for the award of public service contracts does note that some government-owned, operated or controlled contracting entities in the public works and supplies sectors do impose quality management system requirements in their qualified supplier programs. However, ISO 9000 registration is not mandatory under this directive. The EC Commission noted that "quality control certification... exists at the national level in particular service sectors such as the field of engineering. It has been observed that contracting authorities tend to require such certificates whenever a quality assurance body exists in their country. This may have the effect of discriminating against foreign suppliers... The directive should therefore recognize the existence of quality assurance schemes, and reconcile the way in which they are used with the need to grant a fair chance to suppliers from other countries."

## WHO WILL BE ABLE TO CONDUCT MANDATORY EC QUALITY SYSTEM APPROVALS?

When EC directives require the use of a third party in the conformity assessment process, each member country government must provide the EC government with a list of third parties (referred to as "notified bodies") which the member country has determined to be competent to declare that a regulated product conforms to the "essential requirements" spelled out in a particular directive. Member states notify bodies by both conformity assessment method or module (listed in the directive) and by directive to the EC Commission, which then compiles and publishes a list of all such bodies. For example, a quality system registrar could be notified by an EC member country as being competent to conduct quality system approvals in accordance with ISO 9002 (EN 29002) under a specific directive. However, such a body may not be a "notified body" for purposes of other conformity assessment modules or methods listed in the directive or for other directives.

Mandatory quality system approvals or registrations must be conducted by notified bodies. At the present time, notified bodies must be physically located within the geographical boundaries of the European Community. EC member countries can only notify bodies located within their geographical borders.

On September 21, 1992, the EC Council approved a guidance document, "Communication to the Council on the Negotiation of the Agreements between the European Economic Community and Certain

Third Countries on Mutual Recognition in Relation to Conformity Assessment," which provides guidelines for the establishment of mutual recognition agreements with third countries. Notified bodies can only exist in the United States under the provisions of a mutual recognition agreement between the U.S. government and the EC. A mutual recognition agreement (MRA) would allow U.S. entities to perform all required conformity assessment procedures included within the scope of the agreement. Formal discussions between representatives of the U.S. government and the EC on establishing MRAs began on October 20, 1992 in Brussels.

There remains the possibility that some conformity assessment tasks, including quality system audits, may be subcontracted by notified bodies to bodies outside the EC, including organizations in the United States. Such subcontracting would be done at the discretion of the notified body, which would continue to be responsible for audit assessment. Subcontractors must comply with all applicable requirements of the EN 45000 Standard Series. In the case of subcontractors involved in quality system audits, the appropriate European standard is EN 45012.


## HOW CAN I FIND MORE INFORMATION ON NOTIFIED BODIES AND WHAT WILL I LEARN?

A document entitled, "Notified Bodies", which accompanied the EC Mandate, "Communication to the Council on the Negotiation of the Agreements between the European Economic Community and Certain Third Countries on Mutual Recognition in Relation to Conformity Assessment" provides further details on the responsibilities of notified bodies. These requirements will most likely be placed on any U.S. notified bodies. There are several points to note in these documents:

"The notified bodies are, almost by definition, taking on the responsibilities of their national notifying authorities and therefore should remain answerable to them." It is therefore unlikely that the U.S. government will be permitted to notify a body located outside of its territory. Likewise, gaining accreditation from an EC country's accreditation system **does not** mean that a U.S. or other non-EC conformity assessment body can become a notified body. EC member governments may also choose to notify only some of the bodies they have accredited.

Notified bodies must be notified for specific directives and for at least one complete module and any supplementary requirements, though they may be notified for a subset of the products covered by a directive.

Since market surveillance activities are aimed at ensuring the compliance of all involved in placing a product on the market (including the notified bodies), market surveillance activities

will probably not be carried out by notified bodies, or at least not by those involved in the original assessment.

Notified bodies must be independent of their clients or other interested parties. However, a manufacturer's laboratory, for example, might be notified if it is completely independent from the production and commercial department of the firm and if it services production other than just that of the firm.

Notified bodies may also be called on to provide technical guidance on how to apply the provisions of the directives, such as how often quality audits should be conducted. However, such technical clarifications should be discussed between member governments to achieve consensus. Under certain conditions, the notified bodies can also assist the surveillance authorities.


## WHERE CAN I FIND OUT MORE ABOUT THE EC'S SUBCONTRACTING GUIDELINES?

As an interim step pending the establishment of U.S.-EC MRAs or as an alternative to MRAs, some U.S. based registrars are taking advantage of the EC's subcontracting provisions. These provisions allow some conformity assessment tasks, including those in the quality system registration area, to be subcontracted by notified bodies to bodies outside the EC, including organizations in the United States. Subcontracting with EC notified bodies represents an attractive option for a number of U.S. based registrars. However, such subcontracting is done at the discretion of the notified body, which continues to be responsible for the final assessment of product conformity. U.S. and other subcontractors must comply with all applicable requirements contained in the EN 45000 Standard Series. The EC document, Guiding Principles for Subcontracting by "Notified Bodies" pursuant to the Council Resolution of 13 December 1990 Concerning the Modules for the Various Phases of the Conformity Assessment Procedures provides information on the types of tasks that can be subcontracted and the conditions under which subcontracts may be established.


## WILL THE U.S. BE ESTABLISHING MRAS WITH THE EC?

On September 21, 1992, the EC Council approved a guidance document, "The Negotiation of the Agreements Between the European Economic Community and Certain Third Countries on Mutual Recognition in Relation to Conformity Assessment," on seeking mutual recognition agreements with third countries, including the United States. Negotiations for such agreements between the United States and the European Community are being planned in a number of areas based on requests from U.S. industry.

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Preliminary negotiations began on October 20, 1992.  Additional
product/industry specific negotiations are planned for 1993.


## WHAT IS CASE or NVCASE?

At a June 21, 1991 meeting between then Secretary of Commerce
Robert Mosbacher and EC Commission Vice-President Martin
Bangemann, the Secretary proposed that the National Institute of
Standards and Technology (NIST) provide the EC with any
assurances it might require regarding the competence of U.S.
based testing, certification and quality system registration
bodies to conduct conformity assessment activities mandated by
the EC under one or more U.S.-EC MRAs.  NIST has proposed a
program to deal with this responsibility, originally identified
as the Conformity Assessment System Evaluation (CASE) program,
but now entitled the National Voluntary Conformity Assessment
System Evaluation (NVCASE) program.  The proposal was published
in the Federal Register on March 27, 1992, with a closing date
for comments of September 30, 1992.  NIST is preparing to publish
a proposed rule in the Federal Register on the NVCASE program for
public comment in the near future.

The original proposal included the following key concepts:

- The intent of the program would be to recognize qualified
conformity assessment bodies (using international criteria to the
extent possible) to gain greater acceptance of U.S. products in
world markets.

- The program would be voluntary -- no organization would be
required to apply.

- The program would be offered on a fee-for-service basis and
would be self-supporting.

- The program would operate only in "areas related to conformity
assessment where industry would like to have NIST concentrate its
efforts" -- in other words, where industry feels there is a need
and requests such a program.

- The program would provide assurance of the competency of U.S.
conformity assessment bodies to engage in activities in product
areas regulated in foreign countries.  The program would not
operate in areas that are not regulated by a foreign government.

- The program would operate either at the recognition or
accreditation levels for certification, laboratory accreditation,
and quality system registration.

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- The program would not operate at the conformity assessment level. NIST would not act as a certifier, testing laboratory or registrar.

- The program would not operate in product areas covered by other federal regulatory agencies unless such assistance is requested by the agency.

## IS QUALITY SYSTEM REGISTRATION LIKELY TO BE REQUIRED FOR NON-REGULATED PRODUCTS IN THE EC AND ELSEWHERE?

The demand for ISO 9000 registration in Europe and elsewhere seems to be coming primarily from the marketplace as a contractual rather than a regulatory requirement. As conformity to the ISO 9000 standards becomes recognized and required by foreign and domestic buyers and used by manufacturers as a competitive marketing tool, the demand for ISO 9000 compliance is expected to increase in non-regulated areas. It is therefore critical for manufacturers to determine what are their buyers' requirements regarding ISO 9000 compliance.

The degree of interest and pressure specific manufacturers are experiencing from their buyers to seek registration currently varies significantly by industry. In many of the "high tech" or "high safety and health risk" product areas where product reliability is crucial (such as electronic components, aerospace, autos, test equipment and health care products), the market pressure on manufacturers to seek registration is likely to increase.

The U.S. Aerospace Industries Association in its April 1992 Study, <u>Impact of International Standardization and Certification on the U.S. Aerospace Industry</u>, noted that in its industry "...(s)ome RFPs for European and other foreign customers are now including a requirement that potential bidders be ISO 9000-compliant." This growing demand from buyers for registration is being noted by many other industries as well. Procurement authorities and buyers are increasingly including ISO 9000 registration requirements in their purchase contracts. Suppliers desiring to sell to such entities will have to be audited and registered as being in compliance with an ISO 9000 standard under terms acceptable to those buyers.

## WHAT IS EAC?

EAC stands for European Accreditation of Certification, an association of the European national accreditation bodies. The overall objective of the EAC is to create a single European system for recognizing certification/quality system registration bodies that will provide the marketplace with adequate assurance

that certification/registration is equivalent in all European countries. A Memorandum of Understanding (MOU) was signed by Belgium, Denmark, Ireland, the Netherlands, U.K., Germany, Greece, Italy, Portugal, Iceland, Norway, Sweden, and Switzerland on May 22, 1991.

Specific objectives of the EAC, as defined in the MOU, are to: (1) maintain and strengthen market confidence in certificates issued by accredited bodies; (2) establish mutual confidence between participating bodies and promote collaboration and agreements as a means towards a European system of assessment and accreditation; (3) provide the means for a continuous flow of knowledge relevant to assessment and accreditation between participating bodies and other relevant bodies; (4) work towards a multilateral agreement on the equivalence of the operations of the participating bodies and a declaration of their commitment to foster general acceptance of the equivalence of certificates issued by the certification bodies they accredit; and (5) promote the harmonization of the operations of participating bodies.

## WHAT IS THE EOTC AND HOW DOES IT FIT INTO THE PICTURE?

The European Organization for Testing and Certification (EOTC) was created by the EC in April 1990 under a memorandum of understanding with the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Free Trade Agreement (EFTA)[16] countries. The EOTC was formed to promote the mutual recognition of test results, certification procedures, and quality system assessments and registrations in non-regulated product areas throughout the EC and EFTA countries. The EOTC is also responsible for providing technical assistance to the EC Commission in the implementation of some EC legislation, especially in the preparation of mutual recognition agreements with non-EC countries. It is anticipated that there will be a Specialized Committee of the EOTC in the area of Quality Assurance. However, this committee will not be established until after 1992. Nevertheless, the need for expert advice in this area was recognized by the EOTC in July 1991. The European Organization for Quality (EOQ)[17] and the EQS (see below) have

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[16]/ The EFTA countries are Austria, Finland, Iceland, Liechtenstein, Norway, Sweden and Switzerland.

[17]/ A European organization whose mission is to improve quality and reliability of goods and services principally through publications and training. ASQC is an affiliate member.

been offered observership status in EOTC to fill this need. The EOTC is expected to be fully operational in 1993.[18]

## WHAT IS EQS?

EQS, the European Committee for Quality Systems Assessment and Certification, was established in 1989 with membership from both the EC and EFTA countries. The purpose of the EQS is to avoid multiple quality system assessments and registrations of companies or suppliers by harmonizing the rules and procedures used for quality system assessment and registration among members, particularly through the effective implementation of the European Standard, EN 45012 - General Criteria for Certification Bodies Operating Quality System Certification. EQS promotes methods to develop confidence in quality system assessments and registrations carried out by competent quality system registrars. EQS is also responsible for harmonizing the rules for quality system assessment and registration. EQS is currently an advisor to the European Organization for Testing and Certification (EOTC) and is a candidate for serving as a specialized (functional) committee of the EOTC in the quality assurance area.

## WHAT IS EQNET?

EQNET, the European Network for Quality System Assessment and Certification, is a business agreement established in early 1990 by eight quality system registration bodies - AFAQ (France), AIB-Vincotte (Belgium), BSI Quality Assurance (U.K.), DQS (Germany), DS (Denmark), N.V. KEMA (the Netherlands), SIS (Sweden), and SQS (Switzerland).

The purpose of EQNET is to establish close cooperation among members leading to mutual recognition of each other's quality system registration certificates. Each signatory agrees to: (1) promote the recognition of quality system certificates issued by EQNET members; (2) coordinate the work to be performed for quality systems registration of an organization having subsidiaries in several EC/EFTA countries to help such an organization to obtain appropriate quality system (QS) certificates; (3) issue several QS certificates simultaneously after performance of a joint audit; (4) promote bilateral agreements between EQNET members; (5) contribute to the development of operating procedures and promotional materials; and (6) to present information on EQNET. A number of mutual

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[18]/ For information on how to contact the EOTC, see Appendix D.

recognition agreements have been established between EQNET members.

Because EQNET's membership is limited to one not-for-profit quality system registration body per country, it is not a likely candidate for an EOTC agreement group.


## WHAT ELSE IS NEW IN THIS AREA IN THE EC?

Manufacturers should note that some countries have developed additional guidelines for the application of the ISO 9000 standards to specific product sectors, such as medical devices (EN 46000) and aerospace products (EN 2000 and EN 3042).

Some quality system registration programs have also based registration requirements on documents other than ISO 9001, 9002 and 9003.  For example, The U.K.'s Department of Trade and Industry (DITI) has developed a scheme, called TickIT, specifically for software companies which incorporates many of the recommendations in ISO 9000-3: Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software (the guidance document developed by ISO for software suppliers) into its requirements for registration.  The U.K.'s National Accreditation Council for Certification Bodies (NACCB) is offering accreditation to U.K. registrars in the software area under the TickIT scheme.

The U.S. Registrar Accreditation Board (RAB) has set up a committee on the use of ISO 9000-3 in registration and intends to look at issues such as whether there is a need for a similar type of program for software companies in the United States.


## WHAT'S HAPPENING WITH NON-EC EUROPEAN COUNTRIES?

On May 2, 1992, the ministers from the twelve EC and seven EFTA countries signed a treaty designed to establish a nineteen nation free trade area, referred to as the European Economic Area (EEA). While the EC/EFTA countries must still ratify the EEA Treaty, most EFTA countries[19] can be expected to follow the EC's example in encouraging or requiring compliance to the ISO 9000 standards.

Former Eastern Bloc countries may also follow the EC lead as they seek and form closer ties with the European Community.  The EC has entered into bilateral Association Agreements with Poland, Hungary, and Czechoslovakia and is negotiating similar agreements with Bulgaria and Romania.  These agreements will gradually

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[19]/ In a national referendum held on December 6, 1992, Swiss voters rejected the proposal to join the EEA.

establish bilateral free trade areas between the EC and each of the associated countries, with the understanding that the ultimate goal is eventual EC membership for these countries. The EC has also signed Trade Cooperation Agreements with Albania and with the Baltic States. While not as far-reaching as the Association Agreements, these agreements are expected to contribute to the objective of eventually concluding Association Agreements with these countries in the future.

## IS THE U.S. GOVERNMENT PLANNING TO USE THE ISO 9000 STANDARDS?

The U.S. government is beginning to recognize the potential applicability of the ISO 9000 standards to some of its regulatory and procurement activities. U.S. federal government agencies are in the early stages of reviewing the applicability and usefulness of the ISO 9000 standards to their programs. Farthest along is the U.S. Food and Drug Administration's Center for Medical Devices and Radiological Health. The Center plans to replace its Good Manufacturing Practices Guidelines (GMPs) with a version of ISO 9001 by mid-1993.

DOD has adopted the ANSI/ASQC Q90 Standard Series (technically equivalent to the ISO 9000 Standard Series), which means that the standards are listed in the DOD Index of Specifications and Standards (DODISS) and are available to DOD personnel through their publications distribution center. However, the use of the standards has not been included within the Federal Acquisition Regulation (FAR) or the DOD Federal Acquisition Regulation Supplement (DFARS). DOD is currently studying the use of the ANSI Q90 Standard Series and related issues. The Defense Electronics Supply Center (DESC) is considering obtaining ISO 9000 registrar status, depending on the outcome of the study.

The Department of Energy (DOE) is also considering use of the ISO 9000 Series in the planned 1993 publication of its safety guide series which provides supplemental information for contractors on DOE's orders and rules. Other agencies, such as the Federal Aviation Administration (FAA), General Services Administration (GSA), the National Aeronautics and Space Administration (NASA), and the Nuclear Regulatory Commission (NRC) are looking into the usefulness of the ISO 9000 standards within the context of their regulatory and procurement programs.

## ARE MANY COMPANIES SEEKING REGISTRATION IN THE UNITED STATES?

An increasing number of U.S. companies are seeking quality system registration to one of the ISO 9000 or ANSI/ASQC Q90 standards. In the Summer 1992 Registered Company Directory published by CEEM (See Appendix D), over 400 U.S. company sites were listed as being registered to an ISO 9000 standard. This represented an

80% increase from the total listed in the February 1992 issue of directory, and the number of registered U.S. companies continues to grow. CEEM's unofficial records indicate that 621 companies sites had obtained registration as of December 21, 1992.

Some of the motivation for U.S. companies to seek quality system registration results from EC requirements. As noted previously, however, having an approved quality system will not be a blanket requirement for all products. Nevertheless, for suppliers of some products, having an approved quality system will be a key component of the EC's legal requirements. As already discussed, for most of these regulated products, ISO 9000 registration is but one alternative for proving compliance to the essential requirements contained in the so-called "new approach" directives, not an absolute requirement.

However, much of the demand U.S firms are experiencing for ISO 9000 registration in Europe and elsewhere seems to be coming less from regulatory bodies than from the marketplace. As the importance of ISO 9000 registration becomes recognized and required by foreign and domestic buyers and as registration is seen and used by manufacturers as a competitive marketing tool, the demand for ISO 9000 compliance is expected to increase in non-regulated areas.

The degree of interest and pressure felt by U.S. manufacturers to seek registration currently varies significantly by industry. In many of the "high tech" or "high safety and health risk" product areas where product reliability is crucial, the market pressure on U.S. manufacturers to seek registration is likely to be considerable.


## HOW DO YOU SELECT A QUALITY SYSTEM REGISTRAR?

There are currently well over thirty U.S. based organizations offering quality system registration and that number is growing. The credentials of U.S. based registrars vary greatly. Some U.S. registrars have sought accreditation from one or more recognized accreditation bodies. Other U.S. registrars have established mutual recognition agreements with foreign based registrars. Some registrars have followed both courses, seeking mutual recognition agreements while also pursuing accreditation. A number of U.S. based registrars are subsidiaries of parent companies, which are accredited in their home country. In some cases, the registrar's parent company and the U.S. based company have both pursued accreditation by different organizations. A few U.S. based registrars have sought neither accreditation nor mutual recognition agreements with foreign counterparts. These various approaches and the resulting differences in credentials have caused considerable confusion among U.S. companies seeking to select a registrar.

In selecting a registrar, companies must first determine if there are regulatory or marketplace requirements for registration. If there are regulatory requirements, which registrars are approved by the regulatory body to conduct the required registrations? If there are marketplace requirements, is the manufacturer's own declaration of the conformity of his quality system to ISO 9000 acceptable? If not, what registrars' certificates are recognized or accepted in markets where the company wishes to sell?

It also is important for a company to not only ask if a registrar has been accredited, but also to inquire about the product or industry areas in which accreditation has been obtained -- the scope of the accreditation. Registrars are not necessarily accredited to perform work in all product or industry areas. Companies should determine if a registrar's scope of accreditation includes those product or service areas for which the company is seeking registration and if the registrar has conducted assessments of similar types of firms.

Companies should ask the registrar for references. Other questions include: what sort of training, skills and experience do the auditors possess? Are the auditors certified or registered by a nationally recognized scheme? How does a registrar protect confidential information? What sort of appeals process or complaint resolution procedures does the registrar have? What are the registrar's policies and procedures regarding suspension or withdrawal of the registration? Does the registrar adequately respond to complaints or questions in a timely manner? Does the registrar have a good system for providing information to an applicant on deficiencies in the quality system? How soon can the registration be performed? Does the registrar have a backlog? Does the registrar publish and regularly update a list of registered companies, including the scope of registration? In general, how well does the registrar comply with the requirements of ISO/IEC Guide 48?

Cost is, of course, an important consideration. However, a company should look at the total costs involved in obtaining and maintaining a registration. Such costs include: application fees; fees associated with document preparation; fees for quality manual review, as well as for the subsequent review of any needed revisions; cost of the initial visit, including travel and living costs; cost of any follow-up visits, if needed; cost of modifying the scope of registration, if desired; costs associated with surveillance visits and how often such visits will be conducted; and the cost of reassessment upon expiration of the original registration.

## WHO EVALUATES THE COMPETENCE OF REGISTRARS?

In 1989, the Registrar Accreditation Board (RAB) was established as an affiliate of ASQC to develop a program to evaluate the quality of services offered by registrars. RAB issued its first approval in March 1991, and additional firms have been approved since then. RAB and ANSI agreed to form a joint U.S. program in December 1991. Information on the RAB program is available from:

> RAB
> 611 East Wisconsin Ave.
> P.O. Box 3005, Milwaukee, WI 53202
> Phone: 414-272-8575; Fax: 414-765-8661

In February 1992, RAB announced the establishment of an ISO 9000 auditor certification program. RAB has also established requirements for the recognition of an auditor training course. For further information on the program, contact RAB at the above address.[20]

The only European body which accredits registrars outside its geographical borders is the Dutch Council for Accreditation (RvC). It has also accredited registrars in the United States. RAB is currently working towards an agreement with RvC regarding mutual recognition of each other's accreditations.[21]

The Standards Council of Canada (SCC) also has established an accreditation program for quality system registrars, which is open to U.S. registrars.[22]

Programs similar to those of the RAB, RvC, and SCC have been established in a number of other European countries and elsewhere in the world, though they are currently not open to U.S. registrars.[23] However, some U.S. registrars with parent bodies in Europe have had their parent bodies accredited by other

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[20]/ The British Institute for Quality Assurance (IQA) also operates a widely recognized system for the certification of quality system auditors. See Appendix D.

[21]/ For information on how to contact the RvC, see Appendix D.

[22]/ For information on how to contact the SCC program, see Appendix D.

[23]/ ISO has published a "Directory of Quality System Registration Bodies" which includes information on national accreditation bodies. Copies of this directory are available from ANSI. See Appendix D for information on contacting ANSI.

European accreditation bodies, such as the National Accreditation
Council for Certification Bodies (NACCB) in the United Kingdom.

## WHAT IS THE RELATIONSHIP BETWEEN ISO/IEC GUIDE 25 AND ISO 9000?

Both ISO/IEC Guide 25, General Requirements for the Competence of
Calibration and Testing Laboratories, and the ISO 9000 Standard
Series are official documents of the International Organization
for Standardization. ISO/IEC Guide 25 has also been approved by
the International Electrotechnical Commission (IEC).

Developments in the field of quality systems were considered
during ISO/IEC Guide 25 revision in 1990. For laboratories which
serve as suppliers of calibration and test results to industry
and others, ISO/IEC Guide 25 notes in its introduction:

> "Laboratories meeting the requirements of this Guide
> comply, for calibration and testing activities, with
> the relevant requirements of the ISO 9000 series of
> standards, including those of the model described in
> ISO 9002 when they are acting as suppliers producing
> calibration and test results."

In addition, ISO/IEC Guide 25 includes technical requirements for
the operation of a testing laboratory (i.e., participation in
proficiency testing; adherence to specified test methodologies;
and technical competence of laboratory personnel) which are not
addressed in the ISO 9002.

## WHAT CAN NIST'S MANUFACTURING TECHNOLOGY CENTERS DO TO HELP?

NIST operates seven regional manufacturing technology centers
that serve as resource facilities to help manufacturers improve
their competitive position through the application of
manufacturing technology. Several of these centers have
sponsored workshops on ISO 9000. Manufacturers can contact these
centers for specific information about the types of assistance
they offer in the pre-assessment process for ISO qualification.
A list of these centers is included in Appendix E.

## WHAT CAN EDA's TRADE ADJUSTMENT ASSISTANCE PROGRAM DO TO HELP?

The Department of Commerce's Economic Development Administration
(EDA) funds a Trade Adjustment Assistance Program to help ailing
companies. The program operates 12 regional centers. Companies
that have experienced declines in sales and employment, due at
least in part to increasing imports of competitive products, may
apply to the program. The centers can provide financial
assistance to companies, including assisting companies with costs

associated with ISO 9000 registration. A list of these centers is included in Appendix F.

## IS THERE ANY OTHER HELP AVAILABLE?

Some state trade assistance/development authorities, alone or in conjunction with local colleges and universities, also have begun to provide training or offer other assistance. Interested parties should check with their appropriate state agencies.

## WHERE CAN U.S. INDUSTRY GO TO GET ADDITIONAL INFORMATION?

Additional information on U.S., foreign, and international voluntary standards; government regulations; and rules of certification for nonagricultural products is available from:

> National Center for Standards and Certification
>     Information (NCSCI)
> National Institute of Standards and Technology (NIST)
> TRF Bldg. Room A163
> Gaithersburg, MD 20899
> Phone: (301) 975-4040   Fax: (301) 926-1559

For information on the EC 1992 Single Market program, copies of Single Market regulations, background information on the EC, or assistance regarding specific EC trade opportunities or potential problems, contact:

> The Office of EC Affairs
> International Trade Administration, Room 3036
> 14th and Constitution Ave., NW
> Washington, DC 20230
> Phone: (202) 482-5823   Fax: (202) 482-2155

Both agencies are located in the Department of Commerce and can refer interested parties to other sources of information within and outside the federal government.

## APPENDIX A
## INFORMATION AND PUBLICATIONS
## AVAILABLE FROM

Standards Code and Information Program (SCI)
National Institute of Standards and Technology
[SEE LAST PAGE FOR CONTACTS/ADDRESSES]

o The ABC's of Standards-Related Activities in the United States
(NBSIR 87-3576)
   This report is an introduction to voluntary standardization,
product certification and laboratory accreditation for readers
not fully familiar with these topics. It stresses some of the
more important aspects of these fields; furnishes the reader with
both historical and current information on these topics;
describes the importance and impact of the development and use of
standards; and serves as background for using available documents
and services.
Order as PB 87-224309 from NTIS.

o The ABC'S of Certification Activities in the United States
(NBSIR 88-3821)
   This report, a sequel to NBSIR 87-3576, The ABC'S of Standards-
Related Activities in the United States, provides an introduction
to certification for readers not entirely familiar with this
topic. It highlights some of the more important aspects of this
field, furnishes the reader with information necessary to make
informed purchases, and serves as background for using available
documents and services.
Order as PB 88-239793 from NTIS.

o Laboratory Accreditation in the United States (NISTIR 4576)
   This report, a sequel to NBSIR 87-3576 The ABC'S of Standards-
Related Activities in the United States and NBSIR 88-3821 The
ABC'S of Certification Activities in the United States, is
designed to provide information on laboratory accreditation to
readers who are new to this field. It discusses some of the more
significant facets of this topic, provides information necessary
to make informed decisions on the selection and use of
laboratories, and serves as background for using other available
documents and services.
Order as PB 91-194495 from NTIS.

o Questions and Answers on Quality, the ISO 9000 Standard Series,
Quality System Registration, and Related Issues (NISTIR 4721)
   This report provides information on the development, content
and application of the ISO 9000 standards to readers who are
unfamiliar with these aspects of the standards.  It attempts to
answer some of the most commonly asked questions on quality;
quality systems; the content, application and revision of the ISO
9000 standards; quality system approval/registration; European
Community requirements for quality system approval/registration;
and sources for additional help.
Copies not available from SCI.  Order as PB 92-126465 from NTIS.

o <u>Directory of International and Regional Organizations
Conducting Standards-Related Activities</u> (NIST SP 767)
   This directory contains information on 338 international and
regional organizations which conduct standardization,
certification, laboratory accreditation, or other
standards-related activities. It describes their work in these
areas, as well as the scope of each organization, national
affiliations of members, U.S. participants, restrictions on
membership, and the availability of any standards in English.
Copies not available from SCI.  Order as PB 89-221147 from NTIS
<u>or</u> order as Cat. #SP767 from Global Engineering Documents.


o <u>Directory of European Regional Standards-Related Organizations</u>
(NIST SP 795)
   This directory identifies more than 150 European regional
organizations - both governmental and private - that engage in
standards development, certification, laboratory accreditation
and other standards-related activities, such as quality
assurance. Entries describe the type and purpose of each
organization; acronyms; national affiliations of members; the
nature of the standards-related activity; and other related
information.
Copies not available from SCI.  Order as PB 91-107599 from NTIS
<u>or</u> order as Cat. #0258-3 from Global Engineering Documents.


o <u>Standards Activities of Organizations in the United States</u>
(NIST SP 806)
   The directory identifies and describes activities of over 750
U.S. public and private sector organizations which develop,
publish, and revise standards; participate in this process; or
identify standards and make them available through information
centers or distribution channels. NIST SP 806, a revision of NBS
SP 681, covers activities related to both mandatory and voluntary
U.S. standards. SP 806 also contains a subject index and related
listings that cover acronyms and initials, defunct bodies and
organizations with name changes.
Copies not available from SCI.  Order as PB 91-177774 from NTIS
<u>or</u> order as Cat. #SP806 from Global Engineering Documents.


o <u>Directory of Private Sector Product Certification Programs</u>
(NIST SP 774)
   This directory presents information from 132 private sector
organizations in the United States which engage in product
certification activities. Entries describe the type and purpose
of each organization, the nature of the activity, product
certified, standards used, certification requirements,
availability and cost of services, and other relevant details.
Copies not available from SCI.  Order as PB 90-161712 from NTIS.


o <u>Directory of Federal Government Certification Programs</u>
(NBS SP 739)
   This directory presents information on U.S. Government
certification programs for products and services. Entries
describe the scope and nature of each certification program,
testing and inspection practices, standards used, methods of
identification and enforcement, reciprocal recognition or
acceptance of certification, and other relevant details.
Copies not available from SCI.  Order as PB 88-201512 from NTIS.

o <u>Directory of Federal Government Laboratory Accreditation/</u>
<u>Designation Programs</u> (NIST SP 808)
   This directory provides updated information on 31 federal
government laboratory accreditation and similar type programs
conducted by the federal government.  These programs, which
include some type of assessment regarding laboratory capability,
designate sets of laboratories or other entities to conduct
testing to assist federal agencies in carrying out their
responsibilities.  The directory also lists 13 other federal
agency programs of possible interest, including programs
involving very limited laboratory assessment and programs still
under development.
Copies not available from SCI.  Order as PB 91-167379 from NTIS.

o <u>Directory of State and Local Government Laboratory</u>
<u>Accreditation/ Designation Programs</u> (NIST SP 815)
   This directory provides updated information on 21 state and 11
local government laboratory accreditation and similar type
programs.  These programs, which include some type of assessment
regarding laboratory capability, designate private sector
laboratories or other entities to conduct testing to assist state
and local government agencies in carrying out their
responsibilities.  Entries describe the scope and nature of each
program, laboratory assessment criteria and procedures used in
the program, products and fields of testing covered, program
authority, and other relevant details.
Copies not available from SCI.  Order as PB 92-108968 from NTIS.

o <u>Directory of Professional/Trade Organization Laboratory</u>
<u>Organization Laboratory Accreditation/Designation Programs</u> (NIST
SP 831)
   This directory is a guide to laboratory accreditation and
similar types of programs conducted by professional and trade
organizations.  These programs accredit or designate laboratories
or other entities to assist private sector professional
societies, trade associations, related certification bodies,
their membership, as well as government agencies, in carrying out
their responsibilities.  This accreditation or designation is
based on an assessment of the capability of the laboratory to
conduct the testing.  However, the nature of the assessment
varies considerably by organization and program.
Order as SN 003-003-03144-5 from GPO.

o <u>Barriers Encountered by U.S. Exporters of Telecommunications</u>
<u>Equipment</u> (NBSIR 87-3641)
   This report addresses the perceived institution of unreasonable
technical trade barriers by major European trading partners to
the export of telecom products and systems by U.S. companies. The
GATT technical office, which has responsibilities to assist U.S.
exporters to take advantage of trade opportunities, informally
contacted over a period of six months, telecom companies and
agencies to assess the extent of unreasonableness in foreign
national standards, regulations, testing and certification
requirements, and accreditation procedures.
Copies not available from SCI.  Order as PB 88-153630 from NTIS.

o A Review of U.S. Participation in International Standards Activities (NBSIR 88-3698)
   This report describes the role of international standards, their increasingly significant importance in world trade, and the extent of past and current U.S. participation in the two major international standardization bodies - ISO and IEC. The degree of U.S. participation covers the 20 year period 1966-1986. A coarse analysis of data indicates some correlation between U.S. participation and recent export performance for several major product categories.
Copies not available from SCI.  Order as PB 88-164165 from NTIS.

o An Update of U.S. Participation in International Standards Activities (NISTIR 89-4124)
   This report presents updated information on the current level of U.S. participation in ISO and IEC (reference:  NBSIR 88-3698).
Copies not available from SCI.  Order as PB 89-228282/AS from NTIS.

o A Summary of the New European Community Approach to Standards Development (NBSIR 88-3793-1)
   This paper summarizes European Community (EC) plans to aggressively pursue its goal of achieving an "internal market" by 1992 and the standards-related implications of such a program on U.S. exporters.
Order as PB 88-229489/AS from NTIS.

o Trade Implications of Processes and Production Methods (PPMs) (NISTIR 90-4265)
   This report discusses processes and production methods (or PPM's) and their relationship to trade, the GATT Agreement on Technical Barriers to Trade, and traditional product standards used in international commerce. The report provides background information on PPM's, a suggested definition, and the possible extension of their application from the agricultural sector to industrial products.
Order as PB 90-205485 from NTIS.


The following documents are available upon request from SCI.

o tbt news
   This newsletter provides information on government programs and available services established in support of the GATT Agreement on Technical Barriers to Trade (Standards Code). tbt news reports on the latest notifications of proposed foreign regulations; bilateral consultations with major U.S. trade partners; programs of interest to U.S. exporters; and availability of standards and certification information. Subscription is free upon request.

o Technical Barriers to Trade
   This booklet explains the basic rules of the international Agreement on Technical Barriers to Trade negotiated during the Tokyo Round of the Multilateral Trade Negotiations (MTN), and

describes Title IV of the U.S. Trade Agreements Act of 1979 which implements the United States' obligations under the Agreement. The Agreement, popularly known as the Standards Code, was designed to eliminate the use of standards and certification systems as barriers to trade. The booklet describes the functions of the Departments of Commerce and Agriculture, the Office of the U.S. Trade Representative, and the State Department in carrying out the U.S.'s responsibilities.

o "GATT Standards Code Activities"
   This brochure gives a brief description of NIST's activities in support of the Standards Code. These activities include operating the U.S. GATT inquiry point for information on standards and certification systems; notifying the GATT Secretariat of proposed U.S. regulations; assisting U.S. industry with trade-related standards problems; responding to inquiries on foreign and U.S. proposed regulations; and preparing reports on the Standard Code.

o GATT Standards Code Activities of the National Institute of Standards and Technology
   This annual report describes the GATT Standards Code activities conducted by the Standards Code and Information Program for each calendar year. NIST responsibilities include operating the GATT inquiry point, notifying the GATT Secretariat of proposed U.S. Federal government regulations which may affect trade, assisting U.S. industry with standards-related trade problems, and responding to inquiries about proposed foreign and U.S. regulations.

o Free handout material on office activities and standards-related information such as:  government sources of specifications and standards; foreign standards bodies; U.S. standards organizations; and a brochure on the National Center for Standards and Certification Information (NCSCI).

In addition to general inquiry services, the following assistance is also available:

o EC Hotline
   This hotline reports on draft standards of the European Committee on Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). It also provides information on selected EC directives. The recorded message is updated weekly and gives the product, document number and closing date for comments. The hotline number is (301) 921-4164 (not toll-free).

o GATT Hotline
   A telephone hotline provides current information received from the GATT Secretariat in Geneva, Switzerland, on proposed foreign regulations which may significantly affect trade. The recorded message is updated weekly and gives the product, country, closing date for comments (if any) and Technical Barriers to Trade (TBT) notification number. The hotline number is (301) 975-4041 (not toll-free).

o NCSCI provides assistance to U.S. and foreign exporters in obtaining current standards, regulations and certification information for the manufacture of products. To aid foreign exporters, NCSCI also provides directory information of state offices prepared to respond to queries concerning conditions to be met by goods for sale in their state.


TO OBTAIN COPIES OF THESE PUBLICATIONS, CONTACT:

**National Technical Information Service (NTIS)**
5285 Port Royal Road
Springfield, Virginia  22161, USA
Telephone:    (703) 487-4650
**Orders Only:** (800) 553-6847
Fax:          (703) 321-8547


Superintendent of Documents
**U.S. Government Printing Office** (GPO)
Washington, DC   20402, USA
Telephone:  (202) 783-3238
Fax:        (202) 512-2250

**Global Professional Publications**
15 Inverness Way East, P.O. Box 1154
Englewood, CO  80150-1154 USA
Telephone:    (800) 854-7179
Local Phone: (303) 792-2181
Fax:          (303) 792-2192


WHEN REQUESTING PUBLICATION INFORMATION FROM SCI, PLEASE SEND A SELF-ADDRESSED MAILING LABEL TO:

**Standards Code and Information Program** (SCI)
National Institute of Standards and Technology
Administration Building, Room A629
Gaithersburg, Maryland  20899, USA


FOR ASSISTANCE IN OBTAINING INFORMATION ON CURRENT U.S. AND FOREIGN STANDARDS, REGULATIONS AND CERTIFICATION INFORMATION, CONTACT:

**The National Center for Standards and Certification Information** (NCSCI)
National Institute of Standards and Technology
TRF Building, Room A163
Gaithersburg, Maryland  20899, USA
Phone: (301) 975-4040

# APPENDIX B
## SOURCES FOR ORDERING STANDARDS

(Note - copies can be obtained from the respective standards-issuing
organization and/or these sources.)

ORGANIZATION | INFORMATION PROVIDED

American National Standards Institute (ANSI)
11 West 42nd Street, 13th Floor
New York, New York  10036, USA
Telephone: (212) 642-4900
Fax:   (212) 398-0023
       (212) 302-1286 (Orders Only)
Telex:  42 42 96 ANSI UI

ANSI and ANSI approved
  industry standards
International and
  Foreign Standards
Select draft CEN/CENELEC
  standards; draft ISO
  standards


Global Professional Publications
15 Inverness Way East, P.O. Box 1154
Englewood, CO  80150-1154 USA
Telephone:   (800) 854-7179
Local Phone: (303) 792-2181
Fax:   (303) 792-2192

Industry Standards
Federal Standards
  and Specifications
Military Standards
  and Specifications
International and
  Foreign Standards


National Standards Association (NSA)
1200 Quince Orchard Boulevard
Gaithersburg, MD 20878, USA
Telephone:   (800) 638-8094
             (301) 590-2300
Fax:   (301) 990-8378
Telex:   44 6194 NATSTA GAIT

Industry Standards
Federal and Military
  Standards, Specification
  and Related Documents
NATO Standards
Aerospace Standards


General Services Administration (GSA)
Federal Supply Service Bureau
Specifications Branch
490 East L'Enfant Plaza, SW
Suite 8100
Washington, DC 20407, USA
Telephone:  (202) 755-0325 or 755-0326
Fax:    (202) 205-3720

Federal Standards
  and Specifications

| ORGANIZATION | INFORMATION PROVIDED |
|---|---|
| Naval Publications and Forms Center<br>Attn:  NPODS<br>5801 Tabor Avenue<br>Philadelphia, Pennsylvania  19120-5099, USA<br>Inquiries (not for placing orders)<br>Telephone:  (215) 697-2667<br>Fax:  (215) 697-5914 | Dept. of Defense (DOD)<br> adopted documents<br>Naval Publications<br>Military Manuals and<br>Other Related Forms |
| Standardization Document Order Desk<br>Naval Publications Printing Service<br>700 Robbins Avenue, Building 4, Section D<br>Philadelphia, Pennsylvania  19111-5094, USA<br>Telephone:  (215) 697-2179<br>Fax:  (215) 697-2978 | Military Standards,<br>Specifications and<br>Handbooks<br>Federal Standards and<br> Specifications |
| Document Center<br>1504 Industrial Way, Unit 9<br>Belmont, California 94002, USA<br>Telephone: (415) 591-7600<br>Fax: (415) 591-7617 | Industry Standards<br>Federal Standards<br> and Specifications<br>Military Standards<br> and Specifications<br>International and<br> Foreign Standards |
| Information Handling Services (IHS)<br>    (for IHS subscribers only)<br>P.O. Box 1154<br>Iverness Way East<br>Englewood, Colorado  80150, USA<br>Telephone:  (800) 241-7824<br>            (303) 790-0600<br>Fax:  (303) 799-4097<br>Telex:  4322083 IHS UI | International and<br> Foreign Standards<br>Industry Standards<br>Federal Standards<br> and Specifications<br>Military Standards<br> and Specifications<br>Select European<br> Standards (CEN/CENELEC) |
| Standards Sales Group (SSG)<br>9420 Reseda Boulevard, Suite 800<br>Northridge, California  91324, USA<br>Information and Quotes:<br>Telephone:    (818) 368-2786<br>Orders Only: (800) 755-2780<br>Fax:  (818) 360-3804 | International and<br> Foreign Standards,<br> Publications and Other<br> Reference Materials<br>Translations Service<br>U.S./Foreign General<br> Regulatory Compliance<br> Information |

# APPENDIX C
## LIST OF SOME RELEVANT
## STANDARDS

DOD Standards

MIL-Q-9858A, Quality Program Requirements

MIL-I-45208A, Inspection System Requirements


ISO Standards/Guides

ISO/IEC Guide 2, General Terms and their Definitions Concerning Standardization and Related Activities

ISO/IEC Guide 7, Requirements for Standards Suitable for Product Certification

ISO/IEC Guide 16, Code of Principles on Third-Party Certification and Related Standards

ISO/IEC Guide 22, Information on Manufacturer's Declaration of Conformity with Standards or Other Technical Specifications

ISO/IEC Guide 23 - Methods for Indicating Conformity with Standards for Third-Party Certification Systems

ISO/IEC Guide 25, General Requirements for the Competence of Calibration and Testing Laboratories

ISO/IEC Guide 27, Guidelines for Corrective Action to be Taken by a Certification Body in the Event of Misuse of its Mark of Conformity

ISO/IEC Guide 28, General Rules for a Model Third-Party Certification System for Products

ISO/IEC Guide 39, General Requirements for the Acceptance of Inspection Bodies

ISO/IEC Guide 40, General Requirements for the Acceptance of Certification Bodies

ISO/IEC Guide 43, Development and Operation of Laboratory Proficiency Testing

ISO/IEC Guide 44, General Rules for ISO or IEC International Third-Party Certification Schemes for Products

ISO/IEC Guide 45, Guidelines for the Presentation of Test Results

ISO/IEC Guide 46, An Approach to the Review by a Certification Body of its Own Internal Quality System

ISO/IEC Guide 48, Guidelines for Third-Party Assessment and Registration of a Supplier's Quality System

ISO/IEC Guide 53, An Approach to the Utilization of a Supplier's Quality System in Third-Party Product Certification

Draft ISO/IEC Guide 58, Calibration and Testing Laboratory Accreditation Systems - General Requirements for Operation and Recognition (Revision of ISO/IEC Guides 25, 54, and 55)

ISO 8402, Quality - Terminology

ISO 9000 (ANSI/ASQC Q90/EN 29000), Quality Management and Quality Assurance Standards - Guidelines for Selection and Use

ISO 9000-3, Quality Management and Quality Assurance Standards Part 3: Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software

ISO 9001 (ANSI/ASQC Q 91/EN 29001), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing

ISO 9002 (ANSI/ASQC Q 92/EN 29002), Quality Systems - Model for Quality Assurance in Production and Installation

ISO 9003 (ANSI/ASQC Q 93/EN 29003), Quality Systems - Model for Quality Assurance in Final Inspection and Test

ISO 9004 (ANSI/ASQC Q 94/EN 29004), Quality Management and Quality System Elements - Guidelines

ISO 9004-2, Quality Management and Quality System Elements - Part 2: Guidelines for Services

ISO 10011 Part 1, Guidelines for Auditing Quality Systems - Auditing

ISO 10011 Part 2, Guidelines for Auditing Quality Systems - Qualification Criteria for Auditors

ISO 10011 Part 3, Guidelines for Auditing Quality Systems - Management of Audit Programmes

ISO 10012-1, Quality Assurance Requirements for Measuring Equipment - Part 1: Metrological Confirmation System for Measuring Equipment


CEN/CENELEC - EN 45000 and 46000 Standards

EN 45001 General Criteria for the Operation of Testing Laboratories

EN 45002 General Criteria for the Assessment of Testing Laboratories

EN 45003 General Criteria for Laboratory Accreditation Bodies

EN 45011 General Criteria for Certification Bodies Operating Product Certification

EN 45012 General Criteria for Certification Bodies Operating Quality System Certification

EN 45012 General Criteria for Certification Bodies Operating Certification of personnel

EN 45014 General Criteria for Supplier's Declaration of Conformity

EN 45020 (ISO/IEC Guide 2), General Terms and their Definitions Concerning Standardization and Related Activities

prEN 46001, Specific Requirements for the Application of EN 29001 for Medical Devices

## SOURCES FOR ADDITIONAL INFORMATION ON NIST-RELATED
## ACTIVITIES AND ORGANIZATIONS/DOCUMENTS REFERENCED IN THE TEXT

o NIST's National Voluntary Laboratory Accreditation Program (NVLAP), contact:

    NVLAP/NIST
    Building 411, Room A162
    Gaithersburg, MD 20899
    Phone: (301) 975-4042
    Fax:   (301) 926-2884


o The Malcolm Baldrige National Quality Award Program, contact:

    Office of Quality Programs/NIST
    Building 101, Room A537
    Gaithersburg, MD 20899
    Phone: (301) 975-3771


o NIST's Calibration Program, contact:

    Calibration Program/NIST
    Building 411, Room A104
    Gaithersburg, MD 20899-0001
    Phone: (301) 975-2002
    Fax: (301) 926-2884


o NIST's Standard Reference Materials Program, contact:

    Standard Reference Materials Program/NIST
    Building 202, Room 204
    Gaithersburg, MD 20899-0001
    Phone: (301) 975-6776        .
    Fax:   (301) 948-3730


o NIST's Standard Reference Data Program, contact:

    Standard Reference Data Program/NIST
    Building 221, Room A320
    Gaithersburg, MD 20899-0001
    Phone: (301) 975-2208
    Fax:   (301) 926-0416

o The American Society for Quality Control's (ASQC) standards, publications, activities and services; ISO TC 176's activities, contact:

        American Society for Quality Control (ASQC)
        611 East Wisconsin Ave.
        P.O. Box 3005, Milwaukee, WI 53202
        Phone 414-272-8575; Fax: 414-765-8661.


o The Registrar Accreditation Board's (RAB) program, contact:

        Registrar Accreditation Board (RAB)
        611 East Wisconsin Ave.
        P.O. Box 3005, Milwaukee, WI 53202
        Phone 414-272-8575; Fax: 414-765-8661.


o ANSI's activities or to purchase copies of ISO draft/final standards, other documents, magazines, and newsletters, and/or copies of European standards (ENs), contact:

        The American National Standards Institute (ANSI)
        11 West 42nd Street, 13th Floor New York, NY 10036
        Phone: (212) 642-4900
        Fax: (212) 302-1286.


o CEEM's Registered Company Directory, Quality Systems Update newsletter, and other publications, contact:

        CEEM
        10521 Braddock Road
        Fairfax, VA 22032
        Phone: (800) 745-5565 or (703) 250-5900
        Fax:    (703) 250-5313


o  The Aerospace Industries Association's (AIA) activities, contact:

      Aerospace Industries Association
      1250 Eye Street, NW
      Washington, DC  20005
      Phone: (202) 371-8400


o The Netherlands' RvC program, contact:

        Raad voor de Certificatie
        Stationseg 13F
        3972 KA Driebergn
        Phone:  +31 34 381 26 04
        Fax: +31 34 381 85 54


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o The British Institute of Quality Assurance's (IQA) quality system assessor registration program, contact:

    The Secretary to the Board
    National Registration Scheme for Assessors of Quality
    Systems
    The Institute of Quality Assurance
    10 Grosvenor Gardens
    London, U.K.   SWIW ODQ
    Phone: 44-71-730-7154


o The Standards Council of Canada (SCC) Program, contact:

    Standards Council of Canada (SCC)
    45 O'Connor Street, Suite 1200
    Ottawa, Ontario K1P 6N7
    Canada
    Phone: (613) 238-3222
    Fax: (613) 995-4564


o The European Organization for Testing and Certification, contact:

    The EOTC
    Rue Stassart 33, 2nd Floor
    B-1050 Brussels
    Belgium
    Phone: +32 2 519 6969
    Fax: +32 2 519 69 17/19.


o The International Electrotechnical Commission's (IEC) Quality Assessment System for Electronic Components (the IECQ System), contact:

    Electronic Components Certification Board (ECCB)
    Electronic Industries Association (EIA)
    2001 Pennsylvania Ave., NW
    Washington, DC  20006
    Phone: (202) 457-4967
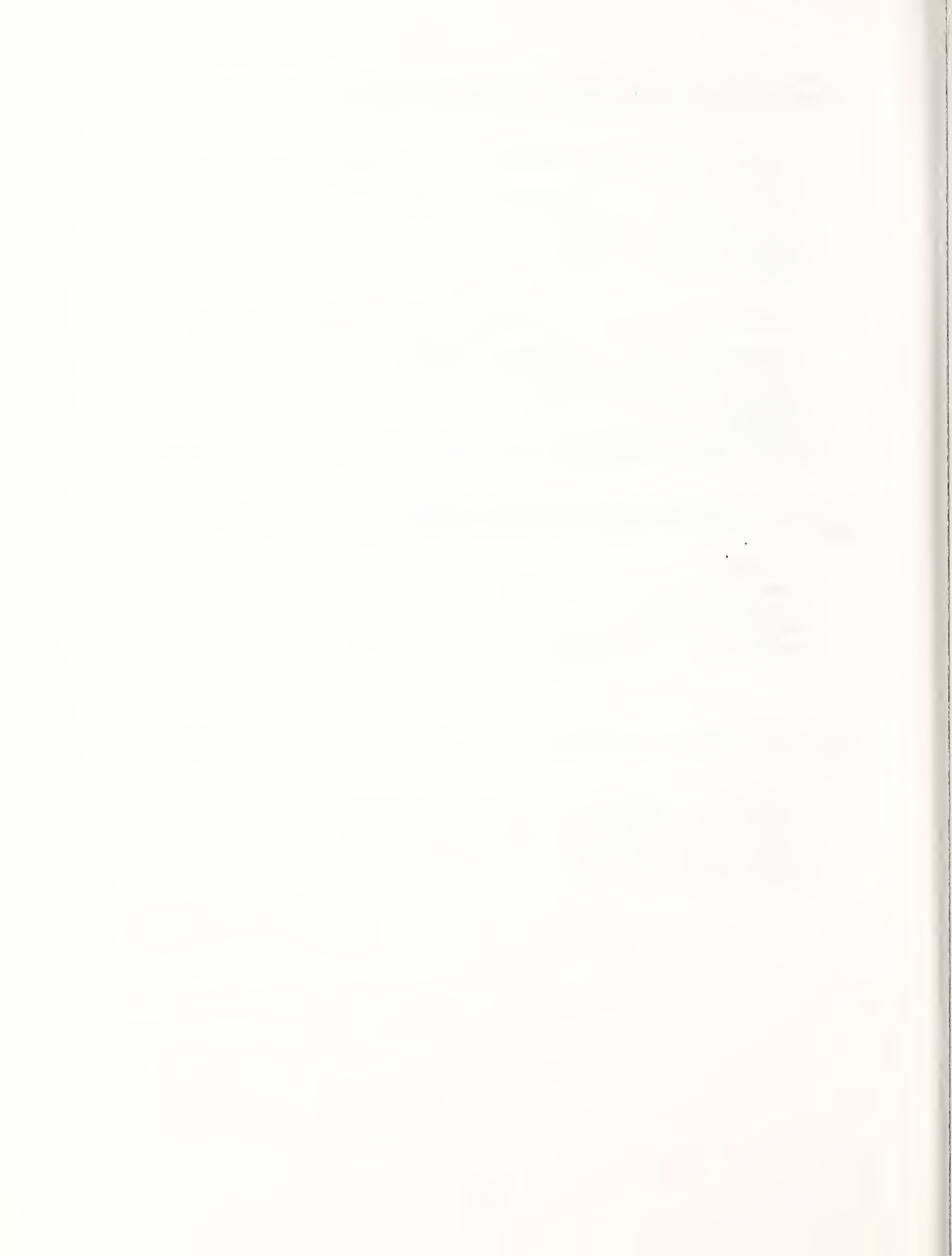
# APPENDIX E
## MANUFACTURING TECHNOLOGY CENTERS (MTCs)[24]

NORTHEAST MTC
Mr. Mark S. Tebbano, Director
Northeast MTC
NY State Science & Technology
Foundation
99 Washington Ave.
Albany, NY  12210
Phone: (518) 473-9746

MIDWEST MTC
Dr. George H. Kuper
Acting Director, Industrial
Technology Institute
P. O. Box 1485
2901 Hubbard Road
Ann Arbor, MI  48109
Phone: (313) 769-4710

SOUTHEAST MTC
Mr. James Bishop, Director
Southeast MTC
P. O. Box 1149
Columbia, SC  29202
Phone: (803) 737-0410

MID-AMERICA MTC
Mr. Paul Clay, President
Mid-America MTC
10561 Barkley, Suite 602
Overland Park, KS  66212
Phone: (913) 649-4333

GREAT LAKES MTC
Dr. George Sutherland,
Director
Great Lakes MTC
2415 Woodland Ave.
Cleveland, OH  44115
Phone: (216) 987-3201

CENTERS ESTABLISHED 7/21/92
Dr. John Chernesky, Director
California MTC
California Community College
1107 Ninth Street
Sacramento, CA  95814
Phone: (310) 355-3060

Ms. Jane Pounds, Director
MTC
Minnesota Technology, Inc.
111 Third Ave.
Minneapolis, MN  55401
Phone: (612) 338-7722

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[24]/ These seven regional centers were established by NIST
to serve as resource facilities to help manufacturers improve
their competitive position through the application of
manufacturing technology.

# TRADE ADJUSTMENT ASSISTANCE CENTERS (TAACs)[25]

NEW ENGLAND TAAC
Richard McLaughlin, Director
New England TAAC
120 Boylston Street
Boston, MA  02116
Phone: (617) 542-2395
Fax:   (617) 542-8457
(CT, RI, VT, NH, MA, ME)

NEW JERSEY TAAC
John Walsh, Acting Director
NJ Econ. Dev. Authority
Capital Place One-CN 990
200 South Warren Street
Trenton, NJ  08625
Phone: (609) 292-0360
Fax:   (609) 292-0368
(NJ)

NEW YORK TAAC
John Lacey, Director
New York TAAC
117 Hawley Street, Suite 102
Binghamton, NJ  13901
Phone: (607) 771-0875
Fax:   (607) 724-2404
(NY)

MID-ATLANTIC TAAC
William Gates, Director
Mid-Atlantic TAAC
486 Norristown Road
Suite 130
Blue Bell, PA  19422
Phone: (215) 825-7819
Fax:   (215) 825-7834
(PA, DE, MD, VA, WV, DC)

SOUTHEASTERN TAAC
Charles Estes, Acting Director
Southeastern TAAC
GA Institute of Technology
Research Institute
151 6th St.
O'Keefe Bldg., Rm. 224
Atlanta, GA  30332
Phone: (404) 894-3858, 6789,
  6106
Fax:   (404) 853-9172
(AL, TN, KY, MS, GA, NC, SC,
FL)

SOUTHWEST TAAC
Robert Velasquez, Director
Southwest TAAC
301 South Frio St., Suite 225
San Antonio, TX  78207
Phone: (210) 220-1240
Fax:   (210) 220-1241
(TX, LA, OK)

MID-AMERICA TAAC
Paul Schmid, Director
Mid-America TAAC
Univ. of Missouri at Columbia
University Place, Suite 1700
Columbia, MO  65211
Phone: (314) 882-6162
Fax:   (314) 882-6156
(MO, KS, AR)

GREAT LAKES TAAC
Margaret Creger, Director
Great Lakes TAAC
University of Michigan
School of Business
Administration
506 East Liberty Street
Ann Arbor, MI  48104-2210
Phone: (313) 998-6213
Fax:   (313) 998-6224
(MI, OH, IN)

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[25]/  The Department of Commerce's Economic Development
Administration (EDA) funds twelve regional Trade Adjustment
Assistance Centers to help ailing companies.

MIDWEST TAAC
Howard Yefsky, Director
Applied Strategies Int'l.
150 N. Wacker Dr, Suite 2240
Chicago, IL  60606
Phone: (312) 368-4600
Fax:   (312) 368-9043
(IL, MN, IA, WI)


ROCKY MOUNTAIN TAAC
Robert Stansbury, Director
Rocky Mountain TAAC
5353 Manhattan Cir., Suite 200
Boulder, CO 80303
Phone: (303) 499-8222
Fax:   (303) 499-8298
(CO, UT, NE, SD, WY, NM)


NORTHWEST TAAC
Ronald Horst, Director
Northwest TAAC
Bank of California Center
900 4th Avenue, Suite 2430
Seattle, WA  98164
Phone: (206) 622-2730
Fax:   (206) 622-1105
(AK, ID, MT, OR, WA)


WESTERN TAAC
Daniel Jimenez, Director
USC - WTAAC
3716 S. Hope Street, Suite 200
Los Angeles, CA  90007
Phone: (213) 743-8427
Fax:   (213) 746-9043
(AZ, CA, NV, HI)

# APPENDIX G
## LIST OF ACRONYMS

**A**
AFAQ ------- ASSOCIATION FRANCAISE POUR L'ASSURANCE DE LA
QUALITE, FRENCH ACCREDITATION BODY AND QUALITY
SYSTEM REGISTRAR
ANSI ------- AMERICAN NATIONAL STANDARDS INSTITUTE, U.S. MEMBER
BODY TO ISO
ANSI/ASQC Q
90 SERIES -- U.S. EQUIVALENT OF THE ISO 9000 SERIES
AQAP-1 ----- ALLIED QUALITY ASSURANCE PUBLICATION 1
ASQC ------- AMERICAN SOCIETY FOR QUALITY CONTROL

**B**
BS 5750 ---- BRITISH EQUIVALENT OF THE ISO 9000 SERIES

BSI -------- BRITISH STANDARDS INSTITUTION

**C**
NIST ------- NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
CASE ------- CONFORMITY ASSESSMENT SYSTEM EVALUATION PROGRAM -
NOW CALLED NVCASE
CD --------- COMMITTEE DRAFT
CE MARK ---- EUROPEAN COMMUNITY MARK
CEN -------- EUROPEAN COMMITTEE FOR STANDARDIZATION
CENELEC ---- EUROPEAN COMMITTEE FOR ELECTROTECHNICAL
STANDARDIZATION

**D**
DESC ------- DEFENSE ELECTRONICS SUPPLY CENTER, DOD
DFARS ------ DOD FEDERAL ACQUISITION REGULATION SUPPLEMENT
DHHS ------- U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIS -------- DRAFT INTERNATIONAL STANDARD
DITI ------- U.K.'S DEPARTMENT OF TRADE AND INDUSTRY
DOC -------- U.S. DEPARTMENT OF COMMERCE
DOD -------- DEPARTMENT OF DEFENSE
DOE -------- U.S. DEPARTMENT OF ENERGY
DOT -------- U.S. DEPARTMENT OF TRANSPORTATION

**E**
EAC -------- EUROPEAN ACCREDITATION OF CERTIFICATION, A
MEMORANDUM OF UNDERSTANDING SIGNED BY EUROPEAN
NATIONAL ACCREDITATION BODIES AT UTRECHT ON MAY 22,
1991
EC --------- EUROPEAN COMMUNITY
EDA -------- ECONOMIC DEVELOPMENT ADMINISTRATION, DOC
EEA -------- EUROPEAN ECONOMIC AREA (A TREATY DESIGNED TO
ESTABLISH A NINETEEN (EC/EFTA) NATION FREE TRADE
AREA)

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EFTA -------  EUROPEAN FREE TRADE ASSOCIATION (AUSTRIA, FINLAND,
              ICELAND, LIECHTENSTEIN, NORWAY, SWEDEN AND
              SWITZERLAND)
EN ---------  EUROPEAN NORM OR STANDARD
EN 29000
SERIES -----  EUROPEAN EQUIVALENT OF THE ISO 9000 SERIES
ENV --------  EUROPEAN PRE-STANDARDS
EOQ --------  EUROPEAN ORGANIZATION FOR QUALITY
EOTA -------  EUROPEAN ORGANIZATION FOR TECHNICAL APPROVALS
EOTC -------  EUROPEAN ORGANIZATION FOR TESTING AND CERTIFICATION
EQNET ------  EUROPEAN NETWORK FOR QUALITY SYSTEM ASSESSMENT AND
              CERTIFICATION, A BUSINESS AGREEMENT ESTABLISHED IN
              EARLY 1990 BY EIGHT QUALITY SYSTEM REGISTRATION
              BODIES
EQS --------  EUROPEAN COMMITTEE FOR QUALITY SYSTEMS ASSESSMENT
              AND CERTIFICATION
ETA --------  EUROPEAN TECHNICAL APPROVAL (APPROVAL BY AN EC
              AUTHORIZED BODY WHICH APPLIES TO CONSTRUCTION
              PRODUCTS FOR WHICH THERE ARE NO EXISTING OR PLANNED
              STANDARDS)
ETSI -------  EUROPEAN TELECOMMUNICATIONS STANDARDS INSTITUTE
```

**F & G**
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FAA --------  FEDERAL AVIATION ADMINISTRATION, DOT
FAR --------  FEDERAL ACQUISITION REGULATION
FDA --------  FOOD AND DRUG ADMINISTRATION, DHHS
GMP --------  GOOD MANUFACTURING PRACTICE GUIDELINES (FDA)
GSA --------  GENERAL SERVICES ADMINISTRATION
```

**H, I & J**
```
HD ---------  HARMONIZED DOCUMENT
IEC --------  INTERNATIONAL ELECTROTECHNICAL COMMISSION
IQA --------  INSTITUTE FOR QUALITY ASSURANCE
ISO --------  INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ITQS -------  RECOGNITION ARRANGEMENT FOR ASSESSMENT AND
              CERTIFICATION OF QUALITY SYSTEMS IN THE INFORMATION
              TECHNOLOGY SECTOR
JAS-ANZ ----  AUSTRALIA/NEW ZEALAND ACCREDITATION BODY FOR QUALITY
              SYSTEM REGISTRARS
```

**M & N**
```
MOU --------  MEMORANDUM OF UNDERSTANDING
MRA --------  MUTUAL RECOGNITION AGREEMENT
MTC --------  MANUFACTURING TECHNOLOGY CENTERS
NAC-QS -----  COMITE NATIONAL POUR L'ACCREDITATION DES ORGANISMES
              DE CERTIFICATION, BELGIUM ORGANIZATION RESPONSIBLE
     •        FOR THE ACCREDITATION OF QUALITY SYSTEM REGISTRARS
NACCB ------  U.K. NATIONAL ACCREDITATION COUNCIL FOR
              CERTIFICATION BODIES
NATO -------  NORTH ATLANTIC TREATY ORGANIZATION
NIST -------  NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
NCSCI ------  NATIONAL CENTER FOR STANDARDS AND CERTIFICATION
              INFORMATION
NRC --------  NUCLEAR REGULATORY COMMISSION
```

```
NVCASE -----  NATIONAL VOLUNTARY CONFORMITY ASSESSMENT SYSTEM
              EVALUATION, FORMERLY THE CASE PROGRAM
NVLAP ------  NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM,
              NIST
```

**O, P & Q**
```
QSR --------  QUALITY SYSTEM REGISTRAR
```

**R & S**
```
RAB --------  REGISTRAR ACCREDITATION BOARD, U.S. ACCREDITATION
              BODY FOR QUALITY SYSTEM REGISTRARS/CERTIFIER OF
              QUALITY SYSTEM AUDITORS, A SUBSIDIARY OF ASQC
RVC --------  RAAD VOOR DE CERTIFICATIE, DUTCH COUNCIL FOR
              CERTIFICATION
SC ---------  SUBCOMMITTEE
SCC --------  STANDARDS COUNCIL OF CANADA, THE CANADIAN BODY
              RESPONSIBLE FOR THE ACCREDITATION OF QUALITY SYSTEM
              REGISTRARS
```

**T**
```
TAAC -------  TRADE ADJUSTMENT ASSISTANCE CENTERS
TC ---------  TECHNICAL COMMITTEE
TC 176 -----  THE ISO TECHNICAL COMMITTEE RESPONSIBLE FOR THE
              DEVELOPMENT OF THE ISO 9000 AND 10000 SERIES
TickIT -----  U.K. QUALITY SYSTEM REGISTRATION SCHEME FOR SOFTWARE
              COMPANIES
              STANDARDS
```

**W**
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WD ---------  WORKING DRAFT
```